

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 524 and 556

Ophthalmic and Topical Dosage Form New Animal Drugs; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of American Home Products Corp. The supplemental NADA provides for topical use of a 0.5 percent moxidectin solution on dairy cattle of breeding age for treatment and control of infections and infestations of certain internal and external parasites. FDA is also amending the regulations to establish a tolerance for moxidectin residues in milk.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7584.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141-099 that provides for use of Cydectin® (moxidectin) 0.5 percent pouron for dairy cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections and infestations of certain gastrointestinal roundworms, lungworms, cattle grubs, mites, lice, and horn flies. The supplemental NADA is approved as of November 2, 1999, and the regulations are amended in 21 CFR 524.1451 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulations are amended in 21 CFR 556.426 to add a tolerance for residues of moxidectin in milk and, editorially, to reflect current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 2, 1999, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 524 and 556 are amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1451 [Amended]

2. Section 524.1451 *Moxidectin* is amended in the first sentence of paragraph (d)(2) by removing the phrase “Beef and non-lactating dairy cattle” and by adding in its place the phrase “Beef and dairy cattle”, and in paragraph (d)(3) by removing the first and second sentences.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

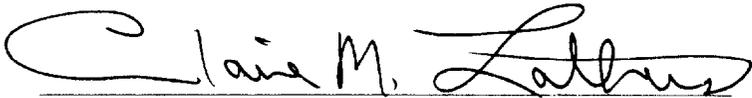
4. Section 556.426 is revised to read as follows:

§ 556.426 Moxidectin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of moxidectin is 4 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerance for parent moxidectin (the marker residue) in edible tissues of cattle is 200 parts per billion (ppb) in liver (the target tissue) and 50 ppb in muscle. The tolerance for parent moxidectin is 50 ppb in milk.

Dated: MAY 29, 2000
May 29, 2000



Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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